C. Furlow (FIB/FOD) 7/18/90

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 18 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: EPA Reg. No. 59639-15 (formerly 239-1281). Naled. Determination of the Need for Processing Studies for Citrus Fruits and the Establishment of Meat/Milk Tolerances. Accession # 263593/ MRID #403766-01 DEB # 6802

From: Jane S. Smith, Chemist
Special Registration Section I
Dietary Exposure Branch
Health Effects Division (H-7509C)

Thru: Andrew Rathman, Section Head
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To: W. Miller/D. Peacock PM Team 16
Insecticide - Rodenticide Branch
Registration Division (H-7505C)

Valent is requesting, again, that a citrus processing study be waived based on the "Naled Citrus Residue" MRID. # 403766-01. Valent claims that since no residues of Naled and DDVP were detected in/on oranges treated at a 4.5X rate and 0 day PHI, processing studies should not be necessary.

Tolerances have been established (40 CFR 180.215) for residues of the insecticide naled, (1,2-dibromo-2,2-dichloro-ethyl dimethyl phosphate), and its conversion product 2,2-dichlorovinyl dimethyl phosphate, expressed as naled, resulting from the application of the pesticide to growing crops or from direct application to livestock and poultry, in or on various racs including grapefruits, lemons, tangerines, and oranges at 3.0 ppm.

The data referenced with this request have been reviewed (see memos dated 9/7/88 by F. Suhre, 3/30/87 by L. Cheng). These data have also been summarized and the deficiencies cited in the updated Residue Chemistry Chapter of the Registration Standard dated 6/8/90. In the conclusion the remaining deficiency is the lack of a "processing study depicting residues of naled and its metabolite DDVP in dried pulp, oil, molasses, and juice processed from citrus fruit bearing measurable weathered residues." And if the residues do concentrate in any product, an appropriate food/feed additive tolerance must be proposed.

The data referenced by Valent in their request (MRID # 403766-01) included a summary of data from Accession # 263593 and data from one field trial conducted on oranges at an exaggerated rate. The exaggerated rate data were not mentioned in either of the previously referenced reviews. The field trial was conducted in Arizona. The four orange trees received three aerial applications to the point of run-off of Dibrome 8E (naled) at prebloom, petal fall, and petal fall plus 9 days. A total of 8.1 lbs a.i./A were applied. The mature oranges for analysis were harvested and frozen on the day of last treatment. Details of Residue Test sheets were also included in MRID # 403766-01 listing all the processed products of citrus fruits and treatment rates; however, no details of processing or residue data were provided. Residues in/on the mature oranges were 0.0 ppm for naled and DDVP. Samples fortified at the same time at 0.01 ppm had recoveries of 67 and 65%. The limit of detection for the method (RM3G-4) was 0.01 ppm. No other details concerning the method were provided.

A summary of the previous data submitted on citrus fruits are as follows;

Naled and DDVP Residues on Mature Citrus Fruit

Location Fruit	No. of Appl.	lbs a.i./A	PHI (days)	ppm Found Naled	DDVP	Total[1]
CA oranges	3	1.8	1	0.03 0.03	0.02 0.02	0.06 0.06
CA lemons	3	1.8	1	0.00 0.00	0.11 0.09	0.19 0.15
AZ oranges	3	1.8	1	0.47 0.51	1.0 1.0	2.2 2.2
CA grapefruit	3	1.8	1	0.02 0.00	0.00 0.00	0.02 0.00

1 naled + DDVP expressed as naled.

Considering <u>all</u> of the residue data that have been submitted on citrus fruits, a single exaggerated rate study that indicates no residues when residues are found at the 1X rate is no justification for the waiving of the processing studies required for citrus fruits. We reiterate the conclusions from the previously referenced reviews and the Registration Standard that residue data are required on processed commodities such as citrus oil, juice, molasses, and dry citrus pulp. If residues of naled and DDVP are found to concentrate upon processing, then appropriate food and feed additive tolerances will need to be proposed. Higher than label application rates on citrus may be necessary in order to obtain meaningful concentration factors.

Conclusions and Recommendations

Residue data are required on processed commodities such as citrus oil, juice, molasses, and dry citrus pulp. If residues of naled and DDVP are found to concentrate upon processing, then appropriate food and feed additive tolerances will need to be proposed. Higher than label application rates on citrus may be necessary in order to obtain meaningful concentration factors.

The registrant should be reminded that the reregistration process is progressing on naled. These data have been requested since at least 1987. It would be in the best interest of the registrant to proceed with the studies without further delay.

cc: RF, Circ, Reg. Std. File, Subject F, JSmith,
PMSD/ISB (CFurlow), RDSchmitt.
RDI: ARathman:07/17/90:EZager:07/17/90
H-7509C:DEB:jss (Misc.Naledcit):JSmith:Rm810F:CM#2:07/17/90